510(k) Summary
Lucent® and Lucent Magnum®

510(k) Number K110632

MAY 2 3 2012

Manufacturer Identification

Submitted by:
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Date Prepared: March 03, 2011

Proprietary Name	Lucent® and Lucent Magnum®
Common Name	Intervertebral Body Fusion Device
Device Classification	21 CFR 888.3080 (Intervertebral Body Fusion Device)
Proposed Regulatory Class	Class II
Device Product Code	MAX

Purpose of this Special 510(k)
This Special 510(k) seeks clearance for a modification to a current system.

Device Description
This product is an intervertebral body fusion device, manufactured from titanium (Ti-6Al-4V) or PEEK-Optima®, for use in lumbar spinal surgery. It may also be referred to as an interbody device or interbody cage. The device is generally box-shaped with various holes throughout its design to allow for the placement of autograft. The exterior of the device has "teeth" or other generally sharp engagement members on the superior and inferior surfaces to help prevent the device from migrating once it is surgically positioned. This modification seeks clearance for the addition of PEEK devices coated with a plasma-sprayed titanium coating.

Intended Use of the Device
Lucent® and Lucent Magnum® are intervertebral body fusion devices intended for spinal fusion procedures at one or two contiguous levels (T1-L5) in skeletally mature patients

with degenerative disc disease (DDD). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis or retrolisthesis at the involved levels. These patients may have had a previous non-fusion spinal surgery at the involved spinal level(s).

This device is intended to be used with supplemental spinal fixation systems that have been cleared for use in the lumbosacral spine (i.e., posterior pedicle screw and rod systems, anterior plate systems, and anterior screw and rod systems).

This device is intended to be used with autogenous bone graft. Patients must have undergone a regimen of at least six (6) months non-operative treatment prior to being treated with this device.

Predicates

The Lucent intervertebral body fusion device is substantially equivalent to the following cleared devices in indications for use, design, function, and materials used.

- Lucent 510(k) K071724 and K073348
- X-Spine Calix PC System (K112036)

Performance Data

A comparison of the data to mechanical testing performance results of the previously cleared Lucent system devices indicates that the additional Lucent devices have the capability to perform at least as well the Lucent device.

Testing performed includes:

- Static Compression Testing as per ASTM F2077
- Static Torsion Testing as per ASTM F2077
- Static Compression-Shear Testing as per ASTM F2077
- Dynamic Compression Testing as per ASTM 2077
- Subsidence Testing as per ASTM F2267
- Wear Characterization as per ASTM F1877, ASTM F2025-06

Coating Characterization testing was performed using coupons.

- Coating Characterization –Static and Dynamic Shear per ASTM F1044
- Coating Characterization – Static Tension per ASTM F1147

All data indicates that the device will perform as intended.

Substantial Equivalence

The Lucent intervertebral body fusion device was shown to be substantially equivalent previously cleared devices in indications for use, design, function, and materials used.

- Lucent 510(k) K071724 and K073348
- X-Spine Calix PC System (K112036)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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MAY 23 2012

Re: K110632
Trade/Device Name: Lucent® and Lucent Magnum®
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: MAX
Dated: May 14, 2012
Received: May 15, 2012

Dear Mr. Kimball:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) K: K110632

Device Name: Lucent®

Indications for Use:
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Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110632